



## **DEPARTMENT OF AGRICULTURE**

### **Food Safety and Inspection Service**

#### **9 CFR Part 424**

**[Docket No. FSIS-2025-0017]**

**RIN 0583-AE07**

### **Removal of Pumped Bacon Sampling Regulations**

**AGENCY:** Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

**ACTION:** Final rule.

**SUMMARY:** FSIS is amending the Federal meat inspection regulations to remove the provisions providing for FSIS' sampling and testing of pumped bacon for nitrosamines. FSIS stopped sampling for nitrosamines in 1998.

**DATES:** The final rule is effective on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**FOR FURTHER INFORMATION CONTACT:** Denise Eblen, Acting Deputy Under Secretary for the Office of Food Safety, at (202) 205-0495 or [docketclerk@usda.gov](mailto:docketclerk@usda.gov) with a subject line of "Docket No. FSIS-2025-0017." Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

**SUPPLEMENTARY INFORMATION:** In 1978, USDA codified provisions for an Agency sampling and testing program (hereinafter the "nitrosamine sampling program") for pumped bacon, consisting of analysis of the product for nitrosamines (43 FR 20992; May 16, 1978; 9 CFR 424.22(b)(1)(i) (previously 9 CFR 318.7(b)(2))). Test results also could be furnished by

establishments (43 FR 32136; July 25, 1978). The Agency later provided alternative procedures for controlling the levels of nitrite added to bacon (51 FR 21731; June 16, 1986) and, in doing so, modified sample selection procedures under the nitrosamine sampling program (9 CFR 424.22(b)(1)(ii)(C) (previously 9 CFR 318.7(b)(4))).

FSIS stopped collecting samples of pumped bacon under the nitrosamine sampling program on October 23, 1998, in part because the program identified very few samples of pumped bacon that contained confirmable levels of volatile nitrosamines. For example, FSIS conducted 174 initial screenings for nitrosamines in pumped bacon from 1994 to 1998. Of these, only 9 samples were presumptively positive for nitrosamines. Only one sample was confirmed positive.

The Agency also stopped administering the program in 1998 because the codified testing methods had become antiquated. The formation of nitrosamines in products depends on several factors, including the cooking method. The regulations provide that all testing for nitrosamines be made on pumped bacon fried at 340 °F for 3 minutes on each side (9 CFR 424.22(b)(1)(i)). However, since the regulations were implemented, greater variability in cooking methods for bacon (e.g., microwave cooking, oven cooking) and greater use of ready-to-eat bacon, meant the codified testing procedures did not necessarily reflect how consumers would actually prepare the product.

Additionally, the nitrosamine sampling program is no longer necessary, given other regulatory requirements control the formation of nitrosamines in pumped bacon. The use of nitrate or nitrite to cure pumped bacon can cause the formation of nitrosamines in the cooked product. As such, FSIS regulations prohibit the use of nitrate in such products and limit the amount of ingoing nitrite to 120 parts per million (9 CFR 424.21 and 9 CFR 424.22). The regulations also require the use of sodium ascorbate or sodium erythorbate in pumped bacon because these substances are curing accelerators and reduce the amount of residual nitrite in the finished product, thus reducing the likelihood of the formation of nitrosamines in the product.

Inspectors can verify that establishments meet the requirements for the use of nitrate, nitrite, and curing accelerators without collecting samples for testing. Therefore, the nitrosamine testing program is no longer necessary.

Given FSIS ended its nitrosamines sampling program and can verify that establishments meet the requirements for pumped bacon through other means, the Agency is removing the program's implementing regulations at 9 CFR 424.22(b)(1)(i) and (ii)(C). This final rule is solely an administrative change to Agency procedure or practice related to its obsolete nitrosamine sampling program. It is therefore excluded from the requirement for notice and comment under the Administrative Procedure Act (5 U.S.C. 553(b)(B)). FSIS regulations will continue to require the use of curing accelerators, prohibit the use of nitrate, and limit the use of nitrite in pumped bacon, which is consistent with FSIS' Hazard Analysis and Critical Control Point requirements (9 CFR part 417), as well as the conditions set out in 9 CFR 424.21 and 424.22.

#### **Executive Orders (E.O.s) 12866, 13563, 14215, and 14192**

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will determine whether a regulatory action is significant as defined by E.O. 12866 and will review significant regulatory actions. OIRA has determined that this final rule is not significant as defined by E.O. 12866. E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 14215 amends E.O. 12866 to ensure Presidential supervision and control of the entire executive branch and to require that all executive departments and agencies submit for review all proposed and final significant regulatory actions to OIRA before publication in the *Federal Register*. The Department has developed the final rule consistent with E.O. 13563 and E.O. 14215.

This final rule is considered an E.O. 14192 deregulatory action.

#### **Congressional Review Act**

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 et seq.), OIRA has designated this final rule as not a major rule as defined by 5 U.S.C. 804(2).

### **Regulatory Flexibility Act**

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; Pub L. No. 104-121, 110 Stat. 857), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required, however, if the head of an agency or an appropriate designee certifies that the rule will not have a significant economic impact on a substantial number of small entities. FSIS has concluded and hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included. The final rule is an administrative change that merely updates the meat product inspection regulations to remove obsolete Agency sampling procedures and practices that have not been implemented since 1998. Because the final rule does not impose any new requirements or restrict production, it is not expected to have any adverse economic effect on small or very small establishments.

### **Executive Order 13175**

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FSIS has assessed the impact of this final rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under Executive Order 13175.

## **Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), FSIS has reviewed the final rule. The Administrator has determined that this rulemaking would not impact information collection, paperwork, or recordkeeping activities.

## **E-Government Act Compliance**

The Department is committed to complying with the E-Government Act of 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

## **E.O. 13132; Federalism Summary Impact Statement**

The final rule has no effect on States and local governments; accordingly, FSIS anticipates that this rule will not have implications for federalism. Therefore, under Section 6(b) of the E.O., a federalism summary is not required.

## **Environmental Impact**

This final rule will not have a reasonably foreseeable significant effect on the quality of the human environment. The rule is an administrative change that merely updates the meat product inspection regulations to remove obsolete Agency sampling procedures and practices that have not been implemented since 1998. Accordingly, this action is appropriately subject to the categorical exclusion from the preparation of an Environmental Assessment or an Environmental Impact Statement as authorized under 7 CFR 1b.4 of the USDA regulations.

## **USDA Non-Discrimination Statement**

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### **Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and

customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

#### **Lists of Subjects in 9 CFR Part 424**

Food additives, Food packaging, Meat inspection, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

#### **PART 424 – PREPARATION AND PROCESSING OPERATIONS**

1. The authority citation for part 424 continues to read as follows:

Authority: 7 U.S.C. 1633, 1901-1906; 21 U.S.C. 451-472, 601-695; 7 CFR 2.18, 2.53.

2. Amend § 424.22 by

- a. Removing and reserving paragraph (b)(1)(i);
- b. Revising paragraph (b)(1)(ii) introductory text; and
- c. Removing paragraph (b)(1)(ii)(C).

The revision reads as follows:

##### **§ 424.22 Certain other permitted uses.**

\* \* \* \* \*

(b) \*\*\*

(1) \*\*\*

(ii) Sodium nitrite may be used at:

\* \* \* \* \*

Done in Washington, DC.

**Denise Eblen,**

Acting Deputy Under Secretary for the Office of Food Safety.